

### Arguments/Remarks

Claim 1 has been amended. Claims 2-30 have been canceled. Claims 31-75 have been added. Claims 1 and 31-75 are in the application upon entry of this amendment. Entry of this amendment, and reexamination and reconsideration of the application are respectfully requested in light of the foregoing amendments and the following remarks.

Claim 1 has been amended to specify that the composition used in the claimed method comprises one or more phenols and an organic sulfonate, the one or more phenols comprising *o*-benzyl-*p*-chlorophenol; *o*-phenylphenol; 2,3-dimethylphenol; *p*-chloro- *m*-cresol; *p*-chloro-*m*-xylanol; 2,4,5-trichlorophenol; or a mixture of two or more thereof. Support for this amendment can be found in the Applicants' specification at page 7, lines 15-30; page 10, lines 17-31; and Examples I-XIV in Tables 1 and 2 on pages 15-16. The phrase "to effect a change in the three-dimensional structure of the prion protein," which is being deleted from claim 1 with this response, had been added by amendment with a previous response. Also, the phrase "the phenol in the composition consisting solely of non-halogenated phenol," which is being deleted from claim 1 with this response, had been added by amendment with a previous response.

New claims 31 and 57 specify that the body comprises a surface or a liquid body. Support for these claims can be found in the Applicants' specification at page 6, lines 28-30.

New claims 32 and 58 specify that the body comprises a surface of a medical, dental or pharmaceutical instrument. Support for these claims can be found in the Applicants' specification at page 6, lines 31-35.

New claims 33 and 59 specify that the body comprises the surface of equipment used in the food or beverage processing industry. Support for these claims can be found in the Applicants' specification at page 6, lines 31-36.

New claims 34 and 60 specify that the body comprises a work surface, wall, floor, ceiling, fermentation tank or fluid supply line in a hospital, industrial facility or research laboratory. Support for these claims can be found in the Applicants' specification at page 6, line 31 to page 7, line 3.

New claims 35 and 61 specify that the body comprises medical waste. Support for these claims can be found in the Applicants' specification at page 7, lines 3-4.

New claims 36 and 62 specify that the body comprises blood, tissue or other body waste. Support for these claims can be found in the Applicants' specification at page 7, lines 3-5.

New claims 37 and 63 specify that the body comprises a room or cage used for housing animals. Support for these claims can be found in the Applicants' specification at page 7, lines 3-6.

New claims 38 and 64 specify that the method is used to decontaminate a disinfection or sterilization system. Support for these claims can be found in the Applicants' specification at page 7, lines 10-11.

New claim 39 specifies that the one or more phenols comprise benzyl-p-chlorophenol, o-phenylphenol, or a mixture thereof. Support for this claim can be found in the Applicants' specification at page 7, lines 20-22, and Tables 1 and 2 on pages 15-16.

New claim 40 specifies that the organic sulfonate comprises C<sub>14</sub>-C<sub>18</sub> sulfonate, sodium C<sub>14</sub>-C<sub>16</sub> sulfonate, alkyl sulfonate, sodium alpha olefin sulfonate, sodium xylene sulfonate, alkylbenzene sulfonate, triethanolamine dodecylbenzene sulfonate, sodium dodecyl benzene sulfonate, calcium dodecylbenzene sulfonate, or a mixture of two or more thereof. Support for this claim can be found in the Applicants' specification at page 10, lines 17-31, and Tables 1 and 2 on pages 15 and 16.

New claim 41 specifies that the organic sulfonate comprises sodium C<sub>14</sub>-C<sub>16</sub> sulfonate. Support for this claim can be found in the Applicants' specification in Table 1 on page 15.

New claim 42 specifies that the organic sulfonate comprises an alpha olefin sulfonate. Support for this claim can be found in the Applicants' specification at page 10, line 23, and Table 2 on page 16.

New claim 43 specifies that the composition comprises o-benzyl-p-chlorophenol, o-phenylphenol and sodium C<sub>14</sub>-C<sub>16</sub> sulfonate. Support for this claim can be found in the Applicants' specification in Table 1 on page 15.

New claim 44 specifies that the composition comprises 2,4,5-trichlorophenol and alpha olefin sulfonate. Support for this claim can be found in the Applicants' specification in Table 2 on page 16.

New claim 45 specifies that at least one of the phenols in the combination of phenols has a Log  $P_c$  value of at least about 2.5. Support for this claim can be found in the Applicants' specification at page 7, line 31 to page 8, line 2.

New claim 46 specifies that the composition is acidic. Support for this claim can be found in the Applicants' specification at page 8, line 10.

New claim 47 specifies that the composition is alkaline. Support for this claim can be found in the Applicants' specification at page 8, lines 16-17.

New claim 48 specifies that the composition includes water. Support for this claim can be found in the Applicants' specification at page 8, lines 21-22.

New claims 49 and 71 specify that prior to contacting the body, the composition is in the form of a concentrate which is diluted with water to form a decontaminate solution. Support for these claims can be found in the Applicants' specification at page 8, lines 22-25.

New claims 50 and 72 specify that prior to contacting the body, the composition is in the form of a concentrate, the concentrate having a total phenol concentration in the range from about 0.1M to about 1.0M. Support for these claims can be found in the Applicants' specification at page 8, lines 31-32.

New claim 51 specifies that the composition further comprises one or more sequestering agents, cosolvents, surfactants, corrosion inhibitors or buffering agents. Support for this claim can be found in the Applicants' specification at page 9, lines 1-5.

New claims 52 and 74 specify that the composition further comprises one or more soluble inorganic salts. Support for these claims can be found in the Applicants' specification at page 10, lines 32-33.

New claim 53 specifies that the composition further comprises water, glycolic acid, dodecyl benzyne sulfonic acid and hexylene glycol. Support for this claim can be found in Table 1 on page 15 of the Applicants' specification.

New claims 54 and 75 specify that the composition further comprises brine. Support for these claims can be found in the Applicants' specification at page 21, lines 1-9.

New claim 55 specifies that the organic sulfonate is a sodium sulfonate. Support for this claim can be found in the Applicants' specification at page 10, lines 15-31, page 11, lines 15-16, and Table 1 on page 15.

New claim 56 is an independent claim which specifies a method of treating a body which is contaminated with infectious prions, the method comprising: contacting the body with a composition comprising one or more phenols and a surfactant to inactivate prions on the body, the one or more phenols comprising *o*-benzyl-*p*-chlorophenol, *o*-phenylphenol, or a mixture thereof. Support for this claim can be found in the Applicants' specification at page 5, lines 5-10; page 7, lines 20-22; page 9, line 4; page 10, lines 11-31; and Examples I-VIII in Table 1 on page 15.

New claim 65 specifies that the one or more phenols further comprise an alkyl, chloro, or nitro-substituted phenol or biphenol, or a carboxylic acid thereof. Support for this claim can be found in the Applicants' specification at page 7, lines 15-18.

New claim 66 specifies that the one or more phenols further comprise phenol; 2,3-dimethylphenol; 3,5-dimethoxyphenol; 2,6-dimethoxyphenol; *p*-tertiary-amylphenol; *p*-chloro-*m*-cresol; *o*-cresol; *p*-cresol; 2,2-methylenbis(*p*-chlorophenol); 3,4-dihydroxybenzoic acid; *p*-hydroxybenzoic acid; caffeic acid; protocatechuic acid; *p*-nitrophenol; 3-phenolphenol; 2,3-dimethoxyphenol; thymol; 4-chloro-3-methoxyphenol; pentachlorophenol; hexachlorophene; *p*-chloro-*m*-xylanol; triclosan; 2,2-methoxy-bis(4-chloro-phenol); para-phenylphenol, or a mixture of two or more thereof. Support for this claim can be found in the Applicants' specification at page 7, lines 18-30.

New claim 67 specifies that the surfactant comprises an anionic, cationic, non-ionic, or zwitterionic surfactant. Support for this claim can be found in the Applicants' specification at page 10, lines 11-12.

New claim 68 specifies that the surfactant comprises an alkylaryl anionic surfactant. Support for this claim can be found in the Applicants' specification at page 10, lines 12-14.

New claim 69 specifies that the surfactant comprises a C<sub>14</sub>-C<sub>18</sub> sulfonate, a sulfonic acid, an ethoxylate, a sarcosinate, a sulfosuccinate, or a mixture of two or more thereof. Support for this claim can be found in the Applicants' specification at page 10, lines 17-20.

New claim 70 specification that the surfactant comprises sodium lauryl ether sulfate, triethanolamine lauryl sulfate, magnesium lauryl sulfate, a sulfosuccinate ester, ammonium lauryl sulfate, an alkyl sulfonate, sodium lauryl sulfate, a sodium alpha olefin sulfonate, an alkyl sulfate, a sulfated alcohol ethoxylate, a sulfated alkyl phenol ethoxylate, sodium xylene sulfonate, an alkylbenzene sulfonate, triethanolamine dodecylbenzene sulfonate, sodium dodecylbenzene sulfonate, calcium dodecylbenzene sulfonate, xylene sulfonic acid, dodecylbenzene sulfonic acid, an N-alkoyl sarcosinate, sodium lauroyl sarcosinate, a dialkylsulfosuccinate, an N-alkoyl sarcosine, lauroyl sarcosine, or a mixture of two or more thereof. Support for this claim can be found in the Applicants' specification at page 10, lines 20-31.

New claim 73 specifies that the composition further comprises one or more sequestering agents, cosolvents, corrosion inhibitors or buffering agents. Support for this claim be found in the Applicants' specification at page 9, lines 1-5.

Claims 1, 5-13, 15-18, 22, 23 and 25-30 have been rejected under 35 U.S.C. §103(a) as unpatentable over Foster (U.S. Patent 7,252,720 B2), Ernst and Race (Ernst et al., "Comparative analysis of scrapie agent inactivation methods," *Journal of Virological Methods*, 41 (1993) 193-202), and Kritzler (U.S. 2004/0106188 A1). The rejection with respect to claims 5-13, 15-18, 22, 23 and 25-30 is now moot in view of the cancellation of these claims. The rejection as it would apply to claim 1, as amended herein, is respectfully traversed.

Foster discloses a method for cleaning a substrate in order to remove adsorbed prion infectivity which comprises washing the substrate with an aqueous salt solution. The salt solution has a salt concentration of at least 1.0 M. The reference indicates that sodium chloride is the preferred salt, but sodium citrate, sodium acetate, sodium gluconate, sodium sulphate, potassium chloride, lithium chloride or ammonium chloride might also be used. The Examiner admits that Foster does not teach the use of a phenol or a sulfonate, both of which are specified in the Applicants' amended claim 1.

Ernst and Race disclose a comparative analysis of scrapie agent inactivation methods. In this reference the authors compare the use of solutions of sodium hydroxide with solutions of a phenolic disinfectant identified as LpH. The reference indicates that LpH has the following formulation:

Ingredient	%
glycolic acid	12.6
p-tertiary amyl phenol	3.0
o-benzyl-p-chlorophenol	6.1
2-phenyl phenol	0.5
hexylene glycol	<5
isopropanol	<10

In this reference the authors describe the efficacy of the LpH formulation at concentrations of 0.9-90% in water and exposure times of 0.5-16 hours against scrapie in an *in vivo* animal model. The authors indicate that LpH is an effective phenol-based disinfectant for use against scrapie. The LpH formulation does not include the use of an organic sulfonate, which is specified in the Applicants' amended claim 1.

Kritzler discloses methods and compositions for treating a surface, suspension or solution contaminated with a PrP<sup>Sc</sup> prion protein or a surrogate thereof. The methods and compositions employ a combination of one or more enzymes effective to cleave a prion protein to fragments having a non-infective molecular weight, and one or more agents selected to favor conformational unfolding of the PrP<sup>Sc</sup> prion protein while not denaturing the one or more enzymes. The agent can be a chemical reagent, for example, an anionic surfactant, a reagent to modify small pH, and also a non-chemical agent to effect physical and/or thermal dynamic conditions such as pressure, temperature, irradiation and other energetic influences which promote folding or unfolding. The agent can be an anionic surfactant used in combination with sonication by ultrasound. Kritzler does not disclose or suggest the combination of the one or more phenols and the organic sulfonate specified in the Applicants' amended claim 1.

Neither Foster nor Kritzler disclose or suggest use of the combination of the one or more phenols and the organic sulfonate specified in the Applicants' amended claim 1. Although Ernst and Race disclose the LpH formulation, which contains o-benzyl-p-chlorophenol and o-phenylphenol, the reference does not indicate that the LpH formulation contains an organic sulfonate. Since none of the cited references disclose the use of an organic sulfonate, which is specified in the Applicants' amended claim 1, it is respectfully submitted that a *prima facie* case of obviousness has not been established against the Applicants' amended claim 1.

As indicated above, Ernst and Race discloses the use of LpH for treating scrapie. This reference is discussed in the Applicants' specification at page 4, lines 21-34. The Applicants' specification contains examples showing formulations within the scope of the Applicants' amended claim 1, as compared to the LpH formulation as well as other phenol-based formulations outside the scope of the Applicants' amended claim 1. In each instance, superior results were obtained when the formulations within the scope of the Applicants' amended claim 1 were used. Specifically, the Examiner's attention is directed to Examples 1 and 2 of the Applicants' specification wherein formulations I-XX as well as the LpH formulation were tested using log reductions. The test procedure is described in the Applicants' specification at page 12, line 27 to page 13, line 21. The log reduction values are measures of the effectiveness of a formulation for inactivating prions. The higher the log reduction value, the better. On page 15 at lines 5-6, the Applicants reported that the log reduction value for the LpH formulation was 4.0. The formulations I-XIV in Tables 1 and 2 on pages 15 and 16 are within the scope of the Applicants' amended claim 1, and for each of these formulations the log reduction value was higher than that for LpH, that is, the values for formulations I-XIV were in the range from 4.1 to 6.7. The value of 6.7 achieved for formulation VII indicated no visible colonies, since the initial count was  $\text{Log}_{10}$  6.7 per mL. On the other hand, in formulations XV-XX in Table 2 on page 17, which did not employ one or more of the phenols specified in the Applicants' amended claim 1 in combination with an organic sulfonate, the log reduction values for each of these were significantly lower, that is, in the range from 2.7-3.8. Thus, it is respectfully submitted that when one or more of the phenols specified in the Applicants' amended claim 1 are used in combination with an organic sulfonate, the log reduction values suggest an unexpected improvement over the prior art LpH formulation as well as the formulations XV-XX.

Applicants respectfully submit that claim 1, as amended, is not obvious over the prior art cited by the Examiner. New claims 31-55 depend from amended claim 1 and are not obvious over the cited references for at least the same reasons that claim 1 is not obvious over such references. Withdrawal of the rejection is believed to be warranted and is respectfully requested.

Claim 56 is not obvious over the prior art cited by the Examiner. New claims 57-75 depend from claim 56 and are also not obvious over the cited references.

Applicants respectfully submit that the application is in condition for allowance. A Notice of Allowance is respectfully requested.

Any additional fees required for the filing of this paper may be charged to Deposit Account No. 18-0988. In the event the Examiner would like to discuss any matter involving this application with the Applicants, he is invited to contact the undersigned attorney by telephone.

Respectfully submitted,

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